

### **REMARKS**

At the outset, applicant's attorney wishes to thank Examiners Frederick F. Krass and Leezah Roberts for the courtesies extended to the applicant Dr. Stockel and the undersigned attorney at the interview held in Examiner Krass' office on February 14, 2006. As a result of such interview, a better understanding was reached as to the differences between the instant invention and the cited prior art and an understanding was also reached as to the course of prosecution of the non-elected species claims in the event that the amended claims are held to be allowable.

### **Election**

Applicant's attorney hereby affirms the provisional election made with traverse by the applicant on November 4, 2005 to prosecute the invention pertaining to a mouthwash containing chlorhexidine-thymol complex as the biocidal complex, as set forth in claim 1 as amended. The election to incorporation of a surfactant comprising Tego Betaine ZF has been effectuated by new claim 21. The election to incorporation of an excipient comprising ethanol has been effectuated by new claim 22. New independent claim 23 reads on the elected species.

To facilitate the prosecution of this application, claims 3, 4, 7, 8 and 12 have been canceled, while claims 2, 5, 6, 9-11 and 13-20 stand withdrawn. Thus the claims now before the Examiner are claims 1 and 21-23.

### **Arrangement of the Specification**

The points raised by the Examiner in pages 4-5 of the outstanding Office Action are well taken. The arrangement of the specification and the headings thereto as described in 37 C.F.R. § 1.77(b) are not mandatory - rather, they are preferred. It should be appreciated that the application was originally prepared by the applicant without the benefit of any input from a registered patent agent/attorney. Applicant's attorney is fully aware of the preferred arrangement and heading of the specification and will revise the specification to meet such arrangement and headings in the event that this application is re-filed. It is respectfully submitted that too many confusing amendments to the specification would be required at this point in time to revise the specification to meet the preferred arrangement and headings.

**Claim Rejections - 35 U.S.C. § 112 - Indefiniteness**

The rejection of claim 12 on the ground of indefiniteness has been mooted by the cancellation of claim 12. Note that new claim 23 (which replaces original claim 12) recites the basis for the weight percentages of each component of the mouthwash.

**Claim Rejections - 35 U.S.C. § 102 - Anticipation**

Claims 1, 3, 4, 7, 8 and 12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Gaffer et al. (US 6,214,320). Claims 1, 3, 4, 7, 8 and 12 also stand rejected under 35 U.S.C. § 102(b) as being anticipated by Polefka et al. (US 5,180,577). It is respectfully submitted that these rejections have been mooted by the amendments to claim 1 and the cancellation of claims 3, 4, 7, 8 and 12. A discussion of the differences between the instant invention as defined by amended claim 1 and new claims 21-23 and the Polefka et al. reference (and the secondary Sköld et al. reference) is set forth below in respect to the rejection of the claims under 35 U.S.C. § 103(a) on the ground of obviousness.

**Claim Rejections - 35 U.S.C. § 103 - Obviousness**

Claims 8 and 12 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Polefka et al. (US 5,180,777) in view of Sköld et al. (Eur. J. Of Oral Sci., 1998, 106, pp. 571-575). In response to this rejection, claims 8 and 12 have been canceled and claim 12 has been replaced by new claim 23. It is respectfully submitted that amended claim 1 and new claims 21-23 are patentable over this combination of prior art references for the reasons presented below.

The present invention is directed to a mouthwash wherein the active ingredient is a **complex** of a cationic biocide and an anionic biocide. In the case of amended claim 1 and new claim 23, due to the election of species, the elected cationic biocide comprises chlorhexidine and the elected anionic biocide comprises thymol. The **complex** is formed by the metathesis reaction of the chlorhexidine with the thymol and such product-by-process limitation has been incorporated in the claims to more clearly distinguish the claims over the cited prior art.

It should be understood that it is sometimes possible to form the complex of the cationic biocide and the anionic biocide by means of an acid-base reaction. Therefore, although a metathesis reaction is recited in the claims in respect to the formation of the chlorhexidine-thymol complex, complexes of other species of cationic biocides with anionic biocides may be formed by an acid-base reaction as clearly stated in the specification, see page 2, lines 6-9 and page 8, lines 6-20.

A cationic biocide such as chlorhexidine as is or likely as a salt such as chlorhexidine gluconate is well-known for use in dental applications such as mouthwashes. In a similar vein, an anionic biocide such as thymol is well-known for use in mouthwashes. Indeed, thymol is the principal active ingredient in the well-known mouthwash branded as Listerine®.

What is not known in the prior art is the concept of forming a complex of a cationic biocide and an anionic biocide by means of a metathesis or acid-base reaction and incorporation such complex in a mouthwash. As brought out by the applicant at the interview held on February 14, 2006, cationic biocides and anionic biocides present in commercially available mouthwashes are employed as is or in the form of their salts. As such, the biocides are effective for only a few seconds after the mouthwash has been rinsed away. However, it has been unexpectedly found that when the biocides are utilized in the mouthwashes in the form of complexes, the complexes provide a slow and extended release in the oral cavity.

Turning to the cited prior art, the principal reference, i.e., the '777 patent discloses a mouthwash containing 0.12 wt.% of chlorhexidine gluconate in the presence of anticalculus phosphoncarboxylic acids. The latter are present in their undisassociated form and therefore there is no reaction that occurs between the chlorhexidine gluconate and the acid. The applicant has carried numerous reactions of this type and it is clear that an anion is required for the metathesis reaction to occur. Thus, it is clear that the '777 patent does not teach of the use of a mouthwash containing a chlorhexidine complex.

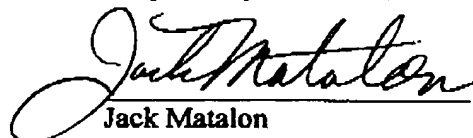
It should also be pointed out that in the '777 patent, Polefka et al. Teach of the use of an amphoteric surfactant, e.g., a Tego betaine (alkylamidopropyl betaine) which interacts with the cationic chlorhexidine gluconate to form a fairly tight ion-pair, thus shielding the cation from forming any potentially water insoluble complexes with any of the excipients in the mouthwash formulation, e.g. fluoride, saccharin ions or phosphoncarboxylate.

It is clear that there is no disclosure whatsoever in the '777 patent of the synthesis of a complex of chlorhexidine or the use of such complex in a mouthwash. The Tego betaine employed in the mouthwashes of the instant invention behaves as a normal surfactant and forms micelles of the neutral chlorhexidine complex, not as a protectant shielding a cation from forming water insoluble complexes with precipitation anions.

The deficiencies of the '777 patent are not overcome by combining the patent with the Sköld et al. article. This article describes a study involving an admixture of chlorhexidine diacetate and thymol in a polymeric varnish which is coated onto teeth to inhibit plaque formation. It bears repeating that the composition described in the Sköld et al. article is an admixture, not a neutral complex between a cationic and an anionic biocide. There is no disclosure, or even a hint or a suggestion, that a new molecular entity is formed such as that which is contained in the mouthwash of the instant invention. Indeed, it would have been impossible to have formed a complex between chlorhexidine diacetate and thymol unless the thymol was first converted to the sodium salt using a strong base.

It is respectfully requested that this application be re-examined and allowed based on the amendments to the claims and the remarks set forth above. Applicant's attorney would welcome a telephone call from the Examiner if she feels that such a discussion would advance the prosecution of this application.

Respectfully submitted,



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